APPLICATION GUIDANCE MATERIAL for the
Maternal and Child Health (MCH) Research Program (CFDA#93.110RS)

This Guidance Material Contains...

Maternal and Child Health Bureau
Health Resources and Services Administration, PHS, DHHS
Parklawn Building, 5600 Fishers Lane
Rockville, MD 20857

Dear Prospective Applicant:

This application guidance material is to be used in preparing new research applications for submission to the Maternal and Child Health (MCH) Research Program. The MCH Research Program uses form PHS 398 (Rev. 4/98). **The instructions accompanying the form contain information which is applicable to the MCH Research Program in part only. An MCHB supplement has been prepared and is enclosed as part of this guidance package.**

Form PHS 398 (Rev. 4/98) consists of two parts. Part A is a **reusable** component that contains detailed instruction on how to prepare the research grant application, including the research plan, samples of face page, budget pages, and other standard form pages that together with the research plan comprise the full research application. It is expected that Part A will be kept by the applicant and used thereafter to prepare future applications. Part B contains blank form pages only and is meant to be for one-time use in the preparation of a research application.

Parts A and/or B of the paper version of Form PHS 398 (Rev. 04/98) can be obtained from the:

(1) Applicant own Office of Sponsored Research;

(2) Grants Information Office, Division of Research Grants
National Institutes of Health (NIH)
Electronic mail address: GrantsInfo@nih.gov
Telephone: (301) 435-0714; and

Grants Management Officer, MCHB

Grants Application Center (CFDA #93.110RS)
1815 N. Fort Myer Drive
Suite 300
Arlington, VA 22209
Telephone: 1-877-477-2123
hrsagac@hrsa.gov

Applicants requesting the paper version of Form PHS 398 (Rev. 04/98) from the HRSA Grants

Application Center will automatically receive the entire guidance material package, including the MCHB Supplemental Instructions for Form PHS 398 (Rev. 4/98).

The electronic versions of Parts A and B of Form PHS 398 (Rev. 4/98) are available on the World Wide Web via the Internet at the following addresses:

http://www.nih.gov/grants/forms.htm

Note, however, that the electronic version of MCHB Supplemental Instructions for form PHS 398 (Rev. 4/98) can only be obtained through the HRSA/MCHB Home Page.

Do not use a font (type) size smaller than #12 anywhere in the application document or it will be returned without review. An example of font size 12 is given below relative to the next smaller (#10) and the next larger (#14) font size:

font size #10	..... maternal and child health
font size #12	..... maternal and child health
font size #14	..... maternal and child health

A new application that was submitted for the first time to the MCH Research Program and disapproved can only be revised and re-submitted twice.

Prospective applicants are encouraged to discuss their research ideas and/or intention to apply with the staff of the program before applying formally. For such inquires and other program related matters, contact:

Gontran Lamberty, Dr.P.H.
Chief, Research Branch
Room 18A-55, Parklawn Building
5600 Fishers Lane

Rockville, MD 20857
Telephone: (301) 443-2190, Fax: (301) 443-4842
e-mail: glamberty@hrsa.gov

The completed research application should be delivered or sent to the HRSA Grants Application Center address listed above. **DO NOT SEND IT TO THE CENTER OF SCIENTIFIC REVIEW (CSR), NATIONAL INSTITUTES OF HEALTH (NIH).** In the event that such misdirection happens, it will be the responsibility of the applicant organization to retrieve the application from the CSR and resubmit same to the address listed above. In misdirection situations, acceptance by the MCHB is not assured for the originally intended deadline unless the application is received 12 weeks prior to the review date. Otherwise, it will be returned to the applicant.

Sincerely,

Ann Drum, DDS, MPH
Acting Director
Division of Research, Training and Education

2. DESCRIPTION OF THE PROGRAM

The Maternal and Child Health (MCH) Research Program is authorized by Title V, Section 502(a)(1) of the Social Security Act. The program is administered by the Division of Research, Training and Education , Maternal and Child Health Bureau (MCHB), Health Resources and Services Administration (HRSA). HRSA is a component of the Public Health Service (PHS), which in turn is part of the Department of Health and Human Services (DHHS). Other components of the PHS are the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Indian Health Service (IHS), the Agency for Health Care Policy and Research (AHCPR), the Agency for Toxic Substances and Disease Registry (ATSDR), and the Centers for Disease Control and Prevention (CDC). The purpose of the MCH Research Program is to support applied research relating to maternal and child health services, which show promise of substantial contribution to the advancement of such services. Findings from the research supported by the MCH Research Program are expected to have potential for application in health care delivery programs for mothers and children.

Other Federal entities are active in maternal and child health research. Foremost among them are the National Institute of Child Health and Human Development (NICHD), the National Center for Nursing Research (NCNR), the Agency for Health Care Policy Research (AHCPR), SAMHSA, and the National Institute of Mental Health (NIMH). MCHB maintains close contacts with NICHD, NCNR, AHCPR, the National Institute of Drug Abuse (NIDA), and NIMH to ensure that duplication of effort does not occur and that new areas of concern receive adequate attention. Funds can be combined to support research that is of mutual interest or that a single entity might not be able to fund independently.

Grants may be made to public or nonprofit institutions of higher learning, and to public or nonprofit private agencies and organizations engaged in research or in maternal and child health or children with special health care needs programs. Grants are not available to individuals even though they may be affiliated with a public or nonprofit organization.

Projects may begin on the first day of any month. A project may be approved at the outset for a project period of not more than 4 years, with an initial budget period of not more than 12 months. Requests for continuation, however, must be approved annually; and support will be dependent upon satisfactory project progress, compliance with the terms and conditions of the grant award, and fund availability.

DEADLINES FOR THE SUBMISSION OF APPLICATIONS AND EARLIEST START DATES

Submission Deadlines, Review, Notification, and Earliest Start Dates

Deadlines for Submission	When Reviewed	Notification to Applicants	Earliest Start Date
March 1	2nd week of June	July	August 1
August 1	2nd week of November	December	January 1

REVIEW OF APPLICATIONS

Applications are screened initially to determine if they are concerned with pertinent maternal and child health applied research issues and if they meet basic requirements, i.e., number of copies, compliance with civil rights, human subject certification, etc. If these requirements are met, the application is then formally accepted for review and assigned to reviewers.

The MCH Research Program uses a review process similar to, but independent from, that of the NIH. The review group is called the Maternal and Child Health Research Review Committee (MCHRRC). It is composed primarily of non-governmental experts appointed for this purpose by the Secretary of DHHS. Committee members are research scientists and clinicians of national stature who are also experienced and knowledgeable in maternal and child health programs. They are selected from the fields of bio-statistics, cultural anthropology, developmental psychology, epidemiology, health services research, nursing, nutrition, obstetrics, pediatrics, sociology, social work, and public health. When the volume of applications received for review and/or their content requires it, special and collateral reviewers are used to supplement the expertise present in the MCHRRC. Except for not voting, special reviewers participate in the review process in the same manner as appointed members of the Committee. Collateral reviewers do their reviews by mail and do not vote.

The criteria for the review of applications are: (a) The importance of the proposed project for MCHB programmatic goals; (b) the project's scientific merit; (c) the reasonableness of the amount of funds requested; (d) the adequacy of the resources available for conducting the proposed research; and (e) the regional or national significance of the anticipated findings. For each application the Committee makes a formal recommendation for approval, disapproval, or deferral. Final decision for action lies with the Associate Director for Maternal and Child Health.

Between 80 and 110 new applications are reviewed each year by the MCHRRC. Approximately 25 % of these applications address medical concerns, 25% behavioral, 40 % health services use and delivery questions, and the remainder, 10%, address epidemiological issues.

Of the new applications reviewed annually, approximately 13 percent are recommended for approval and 87 percent for disapproval/deferral. The rate of approval varies considerably depending on whether the application is new-new (i.e., is being reviewed for the first time) or whether it represents a first or a second revision of an application previously disapproved. These data are presented below.

Number and Percent of New Applications Recommended for Approval According to Type: MCH Research Program, FY 1997.

Type of Application	Approved	Disapproved	Deferred	Total
Total-New	11 13.1%	66 78.6%	7 8.3%	84 100%
New-New	6 8.7%	58 84.1%	5 7.2%	69 100%
New-Revised	5 33.3%	8 53.3%	2 10.3%	15 100%

The approval rate of 33.3% percent for revised, previously disapproved applications reflects the conscious effort of the MCHRRC to be constructive in their reviews as well as the willingness of disapproved applicants to pay attention to the criticisms and suggestions for improvement made by the reviewers. In general, the "gross" approval rate of 13.1 percent (the number of new applications recommended for approval by the committee divided by the total number of new applications reviewed) is relatively low when compared to other Federal research programs, such as NIH. The "net" approval rate (the number of new applications reviewed that are funded divided by the total number of new applications reviewed) compares favorably with other Federal research programs, including NIH.

A detailed summary statement of the review is routinely prepared for all applications reviewed and sent to applicants as soon as possible. The time that it takes for applicants to receive their summary statement varies from 1 to 6 months.

AWARDING OF FUNDS

For applications recommended for approval, the awarding of funds follows a rank order distribution based on the priority scores assigned by members of the Committee. When funds available are exhausted, the remaining proposals are placed in an approved-but-not-funded status and allowed to compete again for the available funds during the following year. If, at the end of this time, the proposals are still not funded, they must be resubmitted in order to receive further consideration.

As a proposal is processed for funding, a review of the budget is made by the grants management and program staffs. Budget negotiations occur with the Principal Investigator (PI) of record and a Notice of Grant Award (NGA) is prepared. The NGA is sent by the Grants Management.
Branch of the Bureau to the business official identified in the application. It is the responsibility of the official to pass on a copy of the NGA to the PI. An award letter, however, is sent directly to the PI announcing the award soon after the NGA has been released to the business official of the grantee institution.

FINAL REPORT AND EXECUTIVE SUMMARY

A final report is required from all supported projects 90 days after completion of the approved project period. The final report is expected to contain a thorough analysis of the data collected to answer the questions for which the research project was originally approved. Applicants are, therefore, advised to plan carefully for the time and resources needed to comply with this requirement. Failure on the part of an investigator to submit an acceptable final report and at the time required not only places in jeopardy future awards for that investigator, but also that of all existing and future MCHB research grants to the institution where the investigator works. The specifics as to the format and content of the final report and the summary will be sent to successful applicants.

PRIORITY RESEARCH ISSUES/QUESTIONS

It has been the practice of the Maternal and Child Health Bureau to re-examine its applied research agenda by periodically convening advisory groups broadly representative of the maternal and child health community. The most recent national advisory group meeting took place in June 1994 and generated a research agenda composed of 266 issues/questions identified to be of critical importance for the mission of the Bureau as it enters the year 2000 and beyond. The agenda was first published in 1996 in a publication entitled *Proceedings of the Fourth National Title V Maternal and Child Health Research Priority Conference.*

The issues/questions comprising the 1994-produced research agenda were evaluated in early FY-1999 and underlying themes were identified and extracted. The extracted themes were supplemented by: (1) The recommendations of the 1999 Special Projects of Regional and National Significance (SPRANS) Report; (2) known program areas the various Divisions of the Bureau have

responsibility for; (3) HRSA, MCHB and the Nation's Year 2010 goals and objectives as declared in respective strategic plans; and (4) assumed State Title V program needs and concerns (i.e., needs assessment, performance evaluation, etc.). Based on the extracted themes and supplemental considerations, a set of 11 tentative and broadly demarcated research agenda areas was constructed keyed to HRSA, MCHB and the Nation's Year 2010 goals and objectives (Table 1). Each of the 11 tentative areas was further explicated using issues/questions derived from the original 1994-produced research agenda. The issues/questions used to define the 11 demarcated areas were scrutinized further by an MCHB Advisory Committee composed of Divisions and Offices representatives. From the larger array of issues/questions, this Committee selected **a sub-set of 15 for "priority" consideration during FY 2000-2003**. **These are presented in Table 2 below**. The "priority" consideration consists of a 0.5 adjustment to the funding score assigned to an application when recommended for approval by the Maternal and Child Health Research Review Committee. The issues/questions remaining under the 11 broadly demarcated areas (See Table 3) have been designated as being also of critical importance to HRSA and MCHB. Field initiated applications addressing this larger array of issues/questions will be accepted for review and considered for funding, but will not be given the special funding consideration, as mentioned above.

Table 1. Research Agenda Areas According to MCHB, HRSA, and Healthy People 2010 Goals and Objectives

Agenda Areas	MCHB		HRSA		Healthy People 2010	
	Goal #	**Objective #**	**Goal #**	**Objective #**	**Goal #**	**Objective #**
I. Quality, Cost, Organization, Access to and Use of Primary Care, Specialty Care and Public Health Services.	**1** **1.1-1.9** **2** **2.1,2.8**		**1** **3**	1.1,1.3, 3.1,3.3,3.5,3.6	**1, 2**	10,12,14,15

		MCHB	HRSA	Healthy People 2010
II.	Response of State Governments and State MCH Units to Federal and State Legislation Creating, Expanding, or Reducing services.	**1** 1.2,1.6-1.9 **2** 2.3-2.5,2.7 **3** 3.5,3.6,3.9,3.10	**1** **1.1,1.4 – 1.6** **2** **2.1,2.3,2.4,2.5** **3** **3.1,3.2, 3.5**	**1, 2** 4,10,12,14,23,26

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	MCHB		HRSA		Healthy People 2010	
III. Development, Testing, and Validation of Screening and Diagnostic Instruments, Including Generic Methodologies to Conduct Need Assessments and Evaluate Performance in States.	**2** **2.4,2.5,2.7** **3** 3.3-3.5		**2** **2.1,2.5** **3** 3.2,3.3		**1,2**	10,12,14

Agenda Areas	MCHB		HRSA		Healthy People 2010	
	Goal #	**Objective #**	**Goal #**	**Objective #**	**Goal #**	**Objective #**
IV Causes of Class, Ethnic, Racial and Urban-Rural Disparities in Physical, Dental and Mental Health, Developmental Competencies and Access to and Use of Services.	**1** **2** **3**	1.1-1.9 2.3 3.9	**1**	1.1,1.2,	**1,2**	10,12

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		MCHB		HRSA		Healthy People 2010	
V	Determinants of Behaviors Associated with Positive and Negative Maternal and Child Health Outcomes and with Preventive, Health Enhancing, and Curative Health Actions.	**1**	1.1,1.2,1.8	**1** **1.1** **2** **2.1** **– 2.3**		**2**	10,12
		2	2.8				
		3	3.7				
VI	Longitudinal Studies of the Health and Normative Development of Minority Children, Children with Special Health Needs, and Children of Low SES, Rural, Migrant, and Homeless Backgrounds.	**1.1-1.9**		**1** **1.1** **2** **2.1** **– 2.5**		**2**	4,12,15
		2	2.1,2.3				
		3	3.9				
					3 3.1,3.3,3.5,3.6		

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	MCHB	HRSA	Healthy People 2010
VII Child, Parental, and Family Coping and Resilience Associated With Significant Injuries, Chronic and Catastrophic Disease Conditions.	**2** 2.5 **3** 3.2,3.7,3.9,3.10	**1** **1.1** **2** **2.1** **3** **3.1**	**1,2** 4,7,9,12,23,26

Agenda Areas	MCHB		HRSA		Healthy People 2010	
	Goal #	Objective #	Goal #	Objective #	Goal #	Objective #
VIII Effects Of Family, Community And Service Systems Contexts On The Physical And Mental Health And Development of Children.	**1**	**1.8, 1.9**		**1** **1.1,1.2**	**2**	10,12
	2 2.1,2.5,2.8			**2**		
		3		**2.5**		
		3.7,3.10				

MCH Research Program Guidance Material (07/01/99)

		MCHB	HRSA	Healthy People 2010
IX	Development, Evaluation, and Validation of MCH Clinical Treatments, Program Interventions, Care Guidelines, Outreach Strategies, and Case Management Approaches	**1** **1.6,1.8,1.9** **2** **2.1-2.8** **3** 3.3-3.10	**1** **1.6** **2** **2.5** **3** **3.3**	**2** 4,10,12,23,26

		MCHB	HRSA	Healthy People 2010
X	Pregnancy, Low Birth Weight, Nutrition and Breastfeeding.	**1.1,1.5,1.8,1.9** **2** 2.8	**2** **2.2,2.3,2.5**	**2** 4,10,12,23,26
XI	Intentional and Unintentional Injuries, Child Neglect and Abuse, Family Violence, Suicide and Emergency Medical Services.	**2** 2.8 **3** 3.2,3.3,3.7	**2** **2.3,2.4** **3** **3.3,3.5,3.8**	**2** 4,7,9,12,23,26

Table 2. Priority Research Issues/Questions: Maternal And Child Health Bureau-FY 2000-2003

I. Quality, Cost, Organization, Access to and Use of Primary Care, Specialty Care and Public Health Services.

5.2.5 Study alternatives for the organization, regionalization, and delivery of comprehensive continuous health services for typically developing and for special health needs children, including ways that primary health care needs of these children can be integrated with the provision of specialized services as exemplified under the concept of "medical home."

6.3.2 Investigate the factors, from both the micro and macro levels, that promote adolescents' timely access to and utilization of health services, with attention to understanding what modifications in service delivery systems, provider training, and young people health education would help adolescents to engage the health care system more appropriately.

II. Response of State Governments and State MCH Units to Federal and State Legislation Creating, Expanding or Reducing Services

8.1.3 Study the processes and complexities involved in having States, communities, and individuals within States, take full advantage of the Medicaid and the Balanced Budget Act (BBA) provisions including CHIP and the authorization for 12 months continuous eligibility for Medicaid and CHIP.

8.1.7 Study how changes in Federal and State welfare laws and States' interpretation and implementation of these laws affects access to and use of maternal and child health services by immigrants. How do the processes involved in the operationalization of these laws in turn affect trends in the use of services (i.e., trimester when prenatal care started) and trends in morbidity and mortality rates (i. e., neonatal death rates) for high immigrant States and specific immigrant groups within states.

III. Development, Testing and Validation of Screening and Diagnostic Instruments, including Generic Methodologies to Conduct Needs Assessments and Evaluate Performance by States

2.6.5 Develop and evaluate new screening and diagnostic technologies for diseases/conditions newly identified as being "genetic."

8.1.8 Develop and test generic methodologies to perform need assessments and evaluate performance at the State and community levels.

IV. Causes of Class, Ethnic, Racial and Urban-Rural Disparities in Physical, Mental and Dental Health, Developmental Competencies, and Access to and Use of Services

3.1.3 Examine the effects of barriers such as racism, prejudice and residential segregation on infant, child, and adolescent health status and health services utilization.

V. Determinants of Behaviors Associated with Positive and Negative Maternal and Child Health Outcomes and with Preventive, Health Enhancement and Curative Health Actions.

2.1.3 Conduct population-based studies on how women decide to seek prenatal care and how this process is arrested or delayed in women who do not receive prenatal care or start later than medically recommended.

VI. Longitudinal Studies of Health and Normative Development in Minority Children, Children with Special Health Needs, and Children of Low SES, Rural, Migrant, and Homeless Backgrounds.

4.3.2 Conduct longitudinal studies on the normative development of children in minority and other at-risk population groups.

VII. Child, Parental and Family Coping and Resilience Associated with Significant Injuries, Chronic and Catastrophic Disease Conditions

1.11.2 Conduct studies on how parents adapt to having a child with disabilities, taking into consideration specific features of the disability as well as parent and family factors existing prior to and after the birth of the affected child.

VIII. Effects of Family, Community and Service Systems Contexts on the Physical and Mental Health and Development of Children

8.1.11 Investigate the processes involved in the transition to employment and adult health care for typically developing and special health care need adolescents with special emphasis on the role that the health care system may play in facilitating or hindering such transitions.

IX. Development, Evaluation, and Validation of MCH Clinical Treatments, Outreach Strategies, Program Interventions, Care Guidelines and Case Management Approaches.

8.1.12 Support randomized controlled studies of the efficacy and cost effectiveness of the various MCHB-developed and promoted Bright Futures guidelines.

X. Pregnancy, Low Birth Weight, Nutrition, and Breastfeeding

2.4.11 Continue to investigate the suspected connection between infections and pre-term onset of labor.

3.8.2 Investigate the determinants of breastfeeding in groups classified according to race, ethnicity and social class.

XI. Intentional and Unintentional Injuries, Child Neglect and Abuse, Family Violence, Suicide and Emergency Medical Services

8.1.13 Study the extent to which children who need emergency medical services receive them, with particular attention to care received (or not received) in hospital emergency departments (EDs).

Table 3. Research Agenda Areas As Defined By Issues/Questions From The 1994-Produced Research Agenda And According To MCHB Divisions of Relevance

Issues/ Questions	I. Quality, Cost, Organization, Access To And Use of Primary Care, Specialty Care And Public Health Services	Division of Relevance
5.2.5*	Study alternatives for the organization, regionalization, and delivery of comprehensive continuous health services for typically developing and for children with special health needs, including ways that the primary health care needs of these children can be integrated with the provision of specialized services as exemplified under the concept of "medical home."	DCSHN DCAFH
6.3.2*	Investigate the factors, from both micro and macro levels, that promote adolescents timely access and utilization of health services, with attention to understanding what modifications in service delivery systems, provider training, and young people health education would help adolescents to engage the health care system more appropriately	DCAFH
1.2.8	Study the minimum standards of comprehensive primary care for women, and the most effective ways of disseminating this information to health care providers and consumers.	DPSWH
1.12.1	Study the different models of organization and operation that are evolving from managed care approaches in relation to how well they address the unique health needs of women and men in the reproductive and parenting phases of the life cycle.	DPSWH DCAFH
2.5.5	Investigate prospectively the safety and cost-effectiveness of early maternal and infant discharge from the hospital, using experimental and quasi-experimental study designs	DPSWH DRTE
2.5.9	Study the changes brought about by the de-regionalization of perinatal services, and the effects of these changes on the availability and distribution of neonatal intensive care.	DPSWH DCAFH

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* = Priority issue/question for FY 2000 – 2003 (see Table 2)

Issues/ Questions		Division of Relevance
5.2.2	Investigate the factors that foster the development of collaborative relationships between provider, parent, child, and school that encourage utilization of the parent=s unique knowledge concerning their child with special health needs and maximizes child and family satisfaction with the care and services received.	DCSHN
5.4.4	Conduct studies that seek to define the components of an effective, comprehensive system of primary care delivery for school-age children. A system that delivers medical as well as dental services, that can be operated in rural as well as suburban areas, that can be incorporated into managed care, and that is distinguished by a high level of integration of primary and specialty care services as exemplified under the concept of "medical home."	DCAFH
6.3.1	Conduct evaluation of "naturally occurring experiments" such as widespread consolidation of health services, expansion of managed care systems, and cost reduction strategies to assess impact on access, utilization, cost, and effectiveness of services rendered to mothers, infants, children and adolescents.	ALL DIVISIONS
8.1.1	Support studies on the content, cost and quality of the medical and dental care received by mothers, infants, children and adolescents, particularly under the Medicaid and CHIPS programs.	ALL DIVISIONS
8.1.2	Conduct studies on the many ways that State and minor subdivisions have operationalized the concept of "medical home" for typically developing and special health needs children, and determine the strengths and weaknesses of the specific models of "medical home" that have evolved.	DCSHN DCAFH

Issues/ Questions	II. Response Of State Governments And State MCH Units To Federal And State Legislation Creating, Expanding Or Reducing Services.	Division of Relevance
8.1.3*	Study the processes and complexities involved in having States, communities, and individuals within States, take full advantage of the Medicaid and the Balanced Budget Act (BBA) provisions including CHIP and the authorization for 12 months continuous eligibility for Medicaid and CHIP.	DPSWH DCAFH
8.1.7*	Study how changes in Federal and State welfare laws and States' interpretation and implementation of these laws affects access to and use of perinatal services by immigrants, and how these processes, which involved in the operationalization of these laws, in turn affect trends in perinatal health services use (i.e., trimester when prenatal care started) and trends in perinatal survival rates (i.e., neonatal death rates) for high immigrant States and specific immigrant groups within these states.	DPSWH DCAFH
5.2.4	Study current policies at the state and national levels that lead to cost shifting between health and education agencies and between insurance and other public programs serving children with special health needs.	DCSHN
6.3.7	Study how and to what extent state Title V units influence state-level government decisions affecting adolescent health (e.g., resource allocation, promulgation of relevant authorization, appropriations, statutes, regulations). What models, approaches, and strategies at the state level have been most effecting in promoting the adolescent health agenda among other types of competing agendas?	DCAFH DPSWH
7.4.1	Study how the policy decisions at state and national levels affect the family ability to meet the health care needs of its members.	ALL DIVISIONS
Issues/ Questions		**Division of Relevance**

7.4.3	Study the interface of different health policy decisions on the legal and human rights of family members (e.g., confidentiality in HIV resting, public funding of family planning efforts, etc.)	ALL DIVISIONS
8.1.4	Conduct studies to determine what drives certain population to initially enroll or not enroll in federally funded programs (particularly Medicaid and CHIP) and to drop out and not re-enroll. What appeals, what does most appeal, and what are the regional and cultural differences between these populations?	DPSWH DCAFH
8.1.5	Study the problem of teenage mothers (e.g., age nineteen) and their children who are falling in and out of the eligibility requirements of the CHIP and Medicaid programs.	DPSWH DCAFH
8.1.6	For CHIPS, conduct studies on the (1) Positive and negative effects of presumptive eligibility (often referred to as welfare for providers); (2) error rates associated with self-declaration, including a comparison of the costs of the error rates versus the cost of maintaining an administrative documentation system; (3) the long and short-term costs of using one-year eligibility, as opposed to six-month eligibility.	DCAFH

Issues/ Questions	III. Development, Testing, And Validation Of Screening And Diagnostic Instruments, Including Generic Methodologies To Conduct Needs Assessments And Evaluate Performance in States.	Division of Relevance
2.6.5*	Develop and evaluate new screening and diagnostic technologies for diseases/conditions newly identified as being "genetic."	DCSHN
8.1.8*	Develop and test generic methodologies to perform need assessments, assessments of unmet needs, and evaluate performance at the State and minor subdivision levels.	DCSHN
1.1.2	Develop instruments to measure racism, sexism, and classism, using different methods, taking into consideration: (1) the various contexts (e.g., workplace, health care setting) in which these practices are expressed,; and (2) the need for instruments that are applicable across different stages of the life cycle.	All Divisions
1.13.3	Study ways of adapting qualitative methods and ethnographic approaches to the collection of health-related information on women and men, particularly in areas where limited empirical work is available to guide prospective hypothesis-testing research.	DPSWH DCAFH
3.2.5	Develop and test feedback methods for conveying to parents' information derived through assessment tools concerning infant strength, and for suggesting strategies to promote infant health, growth, and development.	DCAFH DCSHN
3.3.1	Develop, pilot, and evaluate surveillance systems specifically designed to investigate the effect of social, health, and economic reforms on the lives of infants, children, adolescents and families.	ALL DIVISIONS
3.3.2	Develop, test, and promote collaborative approaches between health departments and researchers in the development of surveillance systems that seek not only to monitor the health status of infants but also to examine the impact of health care reforms as they are placed in operation.	DSCH DPSWH

* = Priority issue/question for FY 2000 – 2003 (see Table 2)

Issues/ Questions		Division of Relevance

3.3.3	Develop, test, and implement models of surveillance systems that interface with existing databases.	DSCH
3.3.4	Develop and test new health indicators that tap family status and captures the nature and quality of the primary and special health care services rendered, the type of insurance coverage, and the services provided by alternative systems of care such as child care, foster care, home care, and early intervention.	All Divisions
4.3.3	Evaluate the validity of current assessment tools for use with minority preschoolers and other at-risk populations.	*DCAFH*
4.3.5	Design and test new instruments and procedures to elucidate the development of complex perceptual and learning skills in typically and atypically developing preschool-age children.	DCAFH DCSHN
5.1.3	Investigate existing data sources that can be tapped and determine the essential data elements needed to create a common database that would identify differences between causes of morbidity and causes of mortality in school-age children, and that would facilitate more informed understanding of ill-health and its determinants in this population group.	DCAFH
6.4.1	Determine which data items/indicators should be collected as part of ongoing surveillance, and which could satisfy important information needs by being collected only once or on a time-limited basis. What are the appropriate units of surveillance—local, state, regional or national- for such ongoing monitoring?	*ALL DIVISIONS*
7.1.4	Develop and evaluate measures and procedures for conducting unobtrusive and systematic observations of within-family processes that impact on health and development, using new advances in video and audio technology and time-sampling techniques.	*ALL DIVISIONS*

Issues/ Questions		Division of Relevance
8.1.9	Assess the reliability and validity of measures now being used by some States and minor subdivisions to report, conduct needs assessment and gauge performance with a view toward their adoption by others and with the intention of using them to conduct cross-site comparability studies of performance.	DCSHN

Issues/ Questions	IV. Causes Of Class, Ethnic, Racial And Urban-Rural Disparities In Physical, Dental And Mental Health, Developmental Competencies And Access To And Use of Services	Division of Relevance
3.1.3*	Examine the effects of barriers such as racism, prejudice, and residential segregation on infant health status and health services utilization.	DCAFH DPSWH
1.1.4	Investigate the coping and survival strategies used by males and females to deal successfully with racism, classism, and sexism in various contexts, including how these strategies are transmitted to female and male children and young adults through the socialization process.	DPSWH DCAFH
1.6.4	Study how racial, ethnic, and cultural differences in family roles and norms influence child outcomes in divorce and other forms of family disruption.	DCAFH
2.4.1	Study how social class, ethnicity and race have protective or deleterious effects on the outcomes of pregnancy, and how the processes engendered by these social positions affect the outcomes.	DPSWH
2.6.3	Investigate the factors responsible for racial, ethnic, and social class differentials in the use of genetic services such as screening, testing, and counseling.	DCSHN DPSWH
3.1.4	Identify and examine the mechanisms behind the ethnic paradoxes (e.g., the considerably lower rates of prematurity, infant mortality and morbidity among Mexican Americans and other recently arrived immigrant groups).	DPSWH
5.1.8	Investigate the underlying causes of socioeconomic differentials in health status among school-age children and ascertain the impact of poverty on special groups such as the homeless, the urban and rural poor, and minority children.	DCSHN DCAFH

***** = Priority issue/question for FY 2000 – 2003 (see Table 2)

Issues/ Questions		**Division of Relevance**
5.5.5	Investigate the unique patterns of socialization in the culture of specific minority groups and the important agents and contexts outside the home that facilitate or hinder resilience in the school-age minority child. Specifically, what is the role of the school environment and the quality of the school.	*DCAFH* DCSHN
5.5.6	Study the factors that determine whether a school-age minority child with special health needs receives active medical management and/or participates in compensatory and early intervention programs.	DCAFH
5.6.1	Study the role that minority fathers play in optimizing their children, medical, mental and dental health and their attainment of developmental competencies.	DCAFH
8.1.10	Study the factors responsible for racial, ethnic, and social class differentials in access to and use of medical, mental and dental services, including screening, testing, and counseling,	All DIVISIONS

Issues/ Questions	V. Determinants Of Behaviors Associated With Positive And Negative Maternal And Child Health Outcomes And With Preventive, Health Enhancement And Curative Health Actions.	Division of Relevance
2.1.3*	Conduct population-based studies on how women decide to seek prenatal care and how this process is arrested or delayed in women who do not receive prenatal care or start later than medically recommended.	DPSWH
1.9.1	Study how high-risk medical and dental health behaviors in women and men affect children, particularly how these behaviors are transmitted to children and thus might become intergenerational.	DPSWH DCAFH
1.9.2	Investigate the relative contribution of specific factors in children and in adults that are most salient in facilitating or inhibiting transmission of high-risk medical and dental health behaviors from parents to children.	DPSWH DCAFH
1.9.3	Study the mechanisms of the family socialization process (e.g., education, modeling, opportunities for practice) as they evolve over time to influence the various medical and dental health practices of children.	DPSWH DCAFH
1.14.3	Investigate aspects of the intimate relationships between women and men that influence health-related behaviors, particularly the decision to seek medical advice, and those factors that support compliance with treatment regimens.	DPSWH
2.1.1	Study the complex male and female behaviors related to pregnancy using different conceptual frameworks, study designs, and methodological approaches.	DPSWH
2.1.2	Investigate the determinants of preconceptional and prenatal care and perinatal care-seeking behavior in women, including the role of social networks and support systems in facilitating the care-seeking process.	DPSWH

Issues/ Questions		Division of Relevance
2.3.3	Study the factors determining the transmission of values and patterns of behavior conducive to adolescent childbearing from one generation to the next.	DPSWH DCAFH
5.1.1	Investigate the determinants of medical, mental and dental health status in school-age children, with particular attention to how parents' medical, mental and dental health status, family life styles, and intergenerational family patterns of behavior/beliefs/attitudes affect child health.	DCAFH
5.3.4	Investigate the child and parental factors that contribute to variation in the long-term developmental trajectory of school-age typically and atypically developing children with respect to health-related behaviors.	DCAFH DCSHN

Issues/ Questions	VI. Longitudinal Studies Of Health And Normative Development Of Minority Children, Children With Special Health Needs, And Children Of Low SES, Rural, Migrant, And Homeless Backgrounds	Division of Relevance
4.3.2*	Conduct longitudinal studies on the normative development of children in minority and other at-risk population groups.	DCAFH DCSHN
1.6.2	Conduct longitudinal studies of the factors associated with long-term outcomes for girls and boys in single-parent, divorced, or remarried families, with special attention to health status, vulnerability and resiliency factors, to supportive relationships available to the child, and to intergenerational transmission of divorce and family instability.	DCSHN DCAFH
1.7.4	Conduct longitudinal studies of how HIV infection affects the psychosocial and parenting functions of men and women, taking into consideration specific class, racial and ethnic variabilities.	DCAFH DCSHN
1.11.1	Conduct longitudinal studies on the consequences of children's chronic disorders on the health of individual mothers and fathers, particularly their physical health.	DCSHN DCAFH
2.3.1	Conduct population-based, longitudinal investigation of the consequences of pregnancy for different categories of adolescents (males and females, younger and older, low and middle socioeconomic status, non-Hispanic whites, African-Americans, Hispanic Americans, etc.).	DPSWH DCAFH
2.3.4	Conduct longitudinal studies on the different pathways to adulthood among adolescent mothers and fathers and the impact of these pathways on the life course of their children.	DCAFH DPSWH

Issues/ Questions		Division of Relevance
4.4.1	Conduct studies that seek to describe longitudinally the evolving father-child relationship from infancy to preschool age, and document how the evolving nature of this relationship affects the mother-child and mother-father relationships.	DCAPH DCSHN
5.3.4	Investigate the child and parent factors that contribute to variation in the long-term developmental trajectory of typically and atypically developing school-age children with regards to health behaviors and outcomes.	DCSHN DCAFH

Issues/ Questions	VII. Child, Parental, And Family Coping and Resilience Associated with Significant Injuries, Chronic And Catastrophic Disease Conditions.*)*	Division of Relevance
1.11.2*****	Conduct studies on how parents adapt to the birth of a child with disabilities, taking into consideration specific features of the disability as well as parent and family factors existing prior to and after the birth of the affected child.	*DPSWH DCSHN DCAFH*
1.7.1	Investigate the consequences of maternal or paternal chronic illness on parental, marital, and gender roles, parent-child and sibling-to-sibling relationships, and overall family functioning.	DCAFH DCSHN DPSWH
1.7.2	Study the factors that determine children's successful or unsuccessful coping with the chronic illness of a parent in relation to family composition and structure, condition-related variables such as severity and visibility, and children's psychological resources such as self-esteem.	DCAFH DCSHN
1.11.3	Investigate the effects of chronic illnesses in children on other children in the family especially relationships between the affected child and siblings, parental attention and guidance, apportioning of parental emotional support among all children, parent-child attachment, etc.	DCAFH DCSHN
2.4.6	Study the psychosocial needs of HIV-positive pregnant women and their family systems as they cope with the chronic, crisis oriented, and usually fatal nature of HIV disease.	DPSWH DCAFH D*CSHN*
3.4.3	Conduct studies of the emotional, behavioral, and regulatory systems of infants and their families who have experienced violent acts and other traumatic experiences.	*DCSHN/ DCAFH*

* = Priority issue/question for FY 2000 – 2003 (see Table 2)

Issues/ Questions	VIII. Effects Of Family, Community And Service Systems Contexts On The Physical And Mental Health And Development of Children.	Division of Relevance
8.1.11*	Investigate the processes involved in the transition to employment and adult health care for typically developing and special health care needs adolescents with special emphasis on role that the health care system may play in facilitating or hindering such transitions.	DCAFH DCSHN
4.3.7	Study the preschool child developmental and contextual transitions to ascertain: (a) what types of resources and mechanism are used by families to meet children's developmental needs; (b) what role the family plays during these transitions; (c) what kinds of support are needed to successfully navigate these transitions; (d) how families identify the support needed and what systems they use to obtain it; and (e) how the provision of a "health home" facilitates transitioning.	DCAFH DCSHN
4.4.2	Investigate the role of context in determining father-child interaction in the preschool years. How do father-child interaction patterns shift across settings and across play and care giving contexts?	DCAFH DCSHN
5.1.9	Study the sources of resilience, coping and protective mechanisms found in low-income families and neighborhoods and determine how these mechanisms can be taught to school-age children to ameliorate the negative effects of poverty.	DCAFH DCSHN
5.2.1	Research the characteristics of foster care environment that promote positive health and developmental outcomes in the school age child with special health needs and develop assessment criteria for determining the appropriateness of foster care placement for such children.	DCAFH DCSHN
5.3.1	Conduct research on the efforts of school age children to successfully navigate transitions from one contextual challenge to another, particularly those efforts that seek to bridge family systems and other settings of relevance to the challenge (e.g., schools).	DCAFH DCSHN

Issues/ Questions		Division of Relevance

5.3.3	Study normative emotional development in the school-age child, particularly as it relates to context-specific mastery and self-regulation.	DCAFH DCSHN
5.3.5	Study the impact of the structure and supervision of after-school hours on child development, health status, and adjustment in school-age children.	DCAFH DCSHN
7.1.1	Study how the individual life course histories of parents prior to family formation affect the nature and dynamics of the family, and the consequences for the health and life course development of parents and children.	DCAFH DCSHN
7.1.2	Investigate the roles and functions of family members in different types of family configurations and the costs and benefits for health and life course development that are associated with the interplay of role, function, and family configuration.	DCAFH DCSHN
7.2.1	Study the factors that erode the capacity of communities to protect ands care for children.	DCAFH DCSHN

* = Priority issue/question for FY 2000 – 2003 (see Table 2)

Issues/ Questions	IX. Development, Evaluation, And Validation Of MCH Clinical Treatments, Outreach Strategies, Program Interventions, Care Guidelines And Case Management Approaches.	Division of Relevance
8.1.12*	Support randomized controlled studies of the efficacy and cost effectiveness of the various MCHB-developed and promoted Bright Future guidelines	*DPSWH DRTE* DCAFH
1.11.5	Evaluate accepted or conventional interventions, as well as new and experimental ones, that seek to facilitate parents' success in negotiating the complex emotional and practical dilemmas facing parents and families who are rearing a child with chronic illness.	DCSHN
1.2.9	Develop, test, and advance educational and health-promoting interventions during women's formative years that help reduce their risk of developing specific disease and conditions in adulthood.	DPSWH DCAFH
1.3.5	Develop, test, and advance educational and health-promoting interventions during men's formative years that help reduce their risk of developing specific diseases and conditions in adulthood.	DPSWH
2.4.9	Develop and evaluate new approaches designed to arrest or prevent birth when preterm labor threatens a pregnancy.	DPSWH
2.5.1	Conduct randomized controlled studies of the effectiveness of the content of prenatal care, including preconceptional care and the nutritional and psychological aspects of care.	DPSWH
2.5.11	Develop and evaluate strategies to inform parents about their infant's condition and treatment and to involve them in decisions to use unproven methods of treatment.	DPSWH DCSHN
3.2.3	Develop interventions to promote infants' functional capacities, including the attainment of new developmental goals and increased capacity for developing age-appropriate functional abilities.	DPSWH DCAFH

Issues/ Questions		Division of Relevance

3.6.3	Develop and evaluate interventions to promote and support breastfeeding among the various racial, ethnic, and social class groups.	DPSWH
5.1.5	Develop and evaluate interventions designed to decrease the role that firearms play in school-age mortality and morbidity associated with homicidal and suicidal acts.	DCAFH
6.2.3	Investigate the relative efficacy of targeted versus comprehensive program approaches to prevention in adolescence. What types of programs work best with whom—when- and why?	DCAFH

* = Priority issue/question for FY 2000 – 2003 (see Table 2)

Issues/ Questions	X. Pregnancy, Low Birth Weight, Nutrition, And Breastfeeding	Division of Relevance
2.4.11*	Continue to investigate the suspected connection between infections and preterm onset of labor.	DPSWH
3.8.2*	Investigate the determinants of breastfeeding in groups classified according to race, ethnicity, and social class.	DPSWH DRTE
1.3.2	Study how exposure of males to workplace and other environmental contaminants affects the integrity and viability of the sperm and how these conditions, in turn, affect reproductive performance, birth outcomes, and child birth.	DPSWH
2.4.5	Evaluate the appropriateness and quality of clinicians' judgements on specific complications of pregnancy as the patient progresses from early, to mid, and to late pregnancy, and through labor and delivery.	DPSWH
2.4.8	Conduct studies to differentiate between types of prematurity (maternal pathology leading to growth retardation and prematurity, for example) that arise from the stressed growth-retarded fetus initiating preterm onset of labor.	DPSWH DCAFH
2.4.12	Investigate, within the Institute of Medicine nutritional guidelines, the nutrition advice that is actually being provided to pregnant women and determine outcomes/consequences.	DPSWH DRTE
2.4.13	Identify, through research, the dietary practices that must benefit fetal growth while moderating fat in the pregnant woman.	DPSWH DRTE
2.5.2	Conduct research that seeks to review and evaluate current prenatal care practice standards.	DPSWH

Issues/ Questions		Division of Relevance
3.6.1	Carry out studies that seek to develop recommendations for the optimal duration of full and partial breastfeeding of infants living under a variety of sociocultural circumstances, in order to maximize the health benefits of the practice.	DPSWH DRTE
3.6.4	Study the impact of policies (e.g., maternity leave, workplace accommodations, child care) designed to support breastfeeding.	DPSWH DRTE

***** = Priority issue/question for FY 2000 – 2003 (see Table 2)

Issues/ Questions	XI. Intentional And Unintentional Injuries, Child Neglect And Abuse, Family Violence, Suicide And Emergency Medical Services.	Division of Relevance
8.1.13*	Study the extent to which children who need emergency medical services receive them, with particular attention to care received (or not received) in hospital emergency departments (EDs).	*DCAFH*
1.4.1	Study the incidence and prevalence of domestic violence by men directed against women in the perinatal period, and the health consequences for the mother, the course of pregnancy, the fetus, and the newborn.	*DPSWH DCAFH*
3.4.2	Conduct qualitative studies of how families and communities define family and community violence and determine their perspective on the most appropriate intervention strategies.	*DCAFH*
3.4.5	Study how violence in the home and community influences parent-child interaction and child rearing practices, with particular attention to using the information generated by the studies to develop positive coping strategies for families living in contexts of violence.	*DCAFH*
4.1.2	Study the family processes that offer familial support and nurturing to children within an ecological and intergenerational context, and study the breakdown of these processes and the subsequent impact on sexual abuse, neglect, and emotional maltreatment.	*DCAFH*
4.2.4	Investigate the unique vulnerability of preschool-age children with special health needs in relation to child abuse.	*DCAFH*
5.1.7	Conduct incidence and prevalence studies of injury morbidity in school-age children, and conduct randomized clinical trials of interventions designed to reduce exposure to the risk of injury in the environment.	*DCAFH*
8.1.14	Conduct studies on the economic consequences of pediatric trauma or severe illness for families and geo-political units	*DCAFH*

Issues/ Questions		Division of Relevance
8.1.15	Study the processes involved in the evaluation and management of minor head trauma, including indications for CT scans, observation and admission	*DCAFH*
8.1.16	Study the various aspects comprising the treatment of acute asthma attacks, including initial assessment and management, predictors of successful outpatient treatments, the role of observation units, and optimal strategies for preventing repeat emergency visits	*DCAFH*

Program Announcements

Each year in HRSA's July-August *Preview* publication, MCHB has a general reminder to the applicant community on the availability of program funds to support new research projects. Similar announcement appears in the *Federal Register*.

3. MCHB SUPPLEMENTAL INSTRUCTIONS FOR RESEARCH APPLICATION FORM PHS 398 (REV. 4/98)

All information contained in the Instructions for PHS 398 (Rev. 4/98) apply to the MCH Research Program unless otherwise noted in the instructions presented below. Note that the material references major sections and headings of the PHS 398 (Rev. 4/98) instructions and gives the page number where the PHS 398 (Rev. 4/98) item specifically referenced is found.

I. SECTION I. PREPARING YOUR APPLICATION

A. INTRODUCTION

1. Page 5. Paragraph 1. Disregard lines 3-7, beginning with "Use the…"

2. Page 5. Paragraph 2. **The Maternal and Child Health Bureau (MCHB) is not listed on page 23.** Instead, call the Grants Management Branch of MCHB at (301) 443-1440. Disregard lines 5-9 beginning with "For further..."

1. Requests for Applications/Program Announcements

1. Page 5. Paragraph 4. MCHB publishes RFA and PA only in HRSA's *Preview and in* the *Federal Register*. For additional instructions contact the Grants Management Branch of MCHB at the telephone number listed above.

A. GENERAL INSTRUCTIONS

1. Page 5. Paragraph 8. Computer-generated facsimiles are accepted by the MCHB.

2. Page 6. Paragraph 1-3.Additional questions regarding page limitations and type size should be directed to the MCH Research Program Office at (301) 443-2190.

3. Page 6. Paragraph 4. Further inquires on legibility should be directed to the MCH Research Program Office.

C. SPECIFIC INSTRUCTIONS

1. Face Page

Item 2. Page 6. Paragraph 6.. Use this item to identify your application as being submitted to the **Maternal and Child Health Research Program of the Maternal and Child Health Bureau** <u>and not to</u> **<u>NIH</u>**. Check "Yes" and then insert the following: "Maternal and Child Health Research Program." Disregard everything else on this item.

Item 3. Page 7. Paragraph 2. Check the "New Investigator" box only if the principal investigator has not previously served as such on any MCHB-supported research project. Disregard everything else on this item.

Item 4. Page 8. Paragraph 4. Send modifications in the Research Plan section required by the IRB to:

Chief, MCH Research Branch
Division of Research, Training and Education
Maternal and Child Health Bureau
Room 18A-55, Parklawn Building
5600 Fishers Lane,
Rockville, MD 20857

Item 5. Pages 8-9. Disregard. Does not apply to the MCH Research Program.

Item 6. Page 9. Paragraph 2. Request no more than 4 years of support. To select an appropriate beginning date for a **New** application, consult the review and award schedule listed on page of this document.

Item 7a. Paragraph 6. See instructions on page of this document.

Item 13. Page 9. Disregard paragraph 16. MCHB is still on paper exchange of information.

Item 13. Page 10. Paragraph 2. MCHB will send the NGA by mail to the grantee institution. The grantee institution is responsible for distributing the NGA, along with any special terms and conditions, to the principal investigator and other appropriate officials within the recipient institution.

2. Description, Performance Sites and Key Personnel (Form Page 2-BB)

Description. Page 10. The MCH Research Program does not participate in the NIH database (CRISP). **However, you are required to fill out this summary/abstract page.**

3. Research Grant Table of Contents (Form Page 3-CC)

Page 11. Paragraph 4. The MCH Research Program requires information in the Research Plan" that is different from that of NIH (See sections a-n of the MCHB Research Plan instructions. Modify **Form Page 3-CC accordingly.**

4. Detailed Budget for Initial Budget Period (Form Page 4-DD)

Applicants should take particular note that the appropriateness of the budget is a factor in the MCH Research Review Committee's decision regarding an application. Members of the Committee are experienced investigators who are familiar with the resources required to carry out a project. Applicants should, thus, submit a budget only for the personnel, supplies, and equipment necessary to carry out the research tasks. The budget rationale should be organized around the tasks involved and should delineate which resources will go to each task. Unusual expenses, especially those normally associated with institutional support (e.g., office or laboratory space, furniture) should be particularly well justified. When data collection or analysis increases or decreases across years of the project, the Committee expects that the budget will reflect these changing demands.

Page 11. **Note**. Line 1. Substitute "MCHB" for "NIH." Line 7, after the word "contact" substitute "the Chief, of MCHB's Research Branch before submitting the application" at (301) 443-2190. Disregard everything thereafter.

Page 11. **Foreign Justification.** Does not apply. The legislation (Title V of the Social Security Act) authorizing funds available for the MCH Research Program does not allow the support of research activities outside the U.S.

Page 13. **Supplies.** The requirements for animal purchases do not apply to the MCH Research Program as animal research is ineligible for MCH research support.

Page 13. **Travel**. Travel to foreign countries is not allowed.

Page 13. **Patient Care Costs.** Does not apply, as no patient care costs are allowed.

Page 13. **Other Expenses.** Animal maintenance, patient travel, donor fees and tuition remission in lieu of salary are not allowed.

9. Research Plan. Page 15. Substitute Aa@ through Ad@ in the instructions to PHS 398 (Rev. 4/98) with what is specified below (a-j). It applies more to the type of research the MCH Research Program typically supports (i.e., health services, epidemiologic and behavioral sciences than to biomedical sciences). Relabel what remains k-n. Be sure also to make corresponding changes in Form Page 3-CC under the AResearch Plan@ heading. For MCHB=s subsections a-j, do not exceed 25 pages in total. You may use any page distribution within this overall limitation.

a. Statement of the Problem. Write a statement of the research problem,indicate the problem=s relevance to maternal and child health or children with special health care needs programs and identify the envisioned application of findings to the clinical management of mothers and children and/or the ways that maternal and child health services are organized and delivered. Within this statement of the problem section, identify one primary and no more than two secondary Aissues/questions@ of the MCHB Research Agenda that the proposed research is addressing.

PHS FORM 398 (Rev. 4/98) requirements on revised application and competitive supplements fully apply to the MCH Research Program. Note that a new application that was submitted for the first time to the MCH Research Program and disapproved can only be revised and resubmitted twice. As PHS Form 398 requires, revised applications should include an "Introduction" section prior to that of the "Statement of the Problem." Begin the "Introduction" section by specifying whether it is the first or second revision; state the MCR number of the prior submission, its title, and cycle of review. **Example: "This is a first revision of application MCR-???-?? Determinants of Racial Disparities in Infant Mortality Rates that was reviewed at the November , 1997 cycle**." Keep in mind that the function of the "Introduction" section is to let the reviewers know that the concerns raised in the earlier review have been addressed in the revised protocol, inform them where in the revised protocol the concerns have been addressed, and offer rationales for the changes and additions made. Note also that the "Introduction" section is not intended to be a repository of substantive, technical information. That type of information belongs in the "Research Plan"

Competing continuation (often called "competing extension") requests should begin the Statement of the Problem section by identifying the project by its MCJ- number, title, the originally approved project period, and the additional time that is being requested. A justification for the extension should follow. If the reason for submitting a competing extension application is to conduct new work deriving from the prior grant (i.e., a spin-off research question, longitudinal follow up of the original study cohort), a full blown application must be submitted covering sections **a- n** of the research plan. A progress report on the original grant is required and should provide a description of the progress made since the beginning of the project. What has yet to be done and in what time frame should be stated clearly also. **Competing extension applications pursuing new work should keep the title of the original investigation and add to it a "__Phase 2 or 3, etc.**"

If the competing extension application is strictly to complete activities which were part of the originally approved project period and no new work is proposed, there is no need to proceed with items **a-n** described below in the section having to do with the Research Plan. The body of the application, however, should contain sufficient information from the original grant application to allow evaluation of the proposed extension in relation to the goals of the original application, including a description of the events that led to the need for the extension and a statement of how the extension of time and funds, or the lack of them, will influence the attainment of the original objectives of the project. A progress report for the original investigation is also required.

b. Review of the Literature. Review critically the pertinent literature with respect to the research problem being pursued, including, when warranted, assessment of research methodologies and study designs employed, significance of the findings and assertions, and reliability and validity of the findings. Specifically, identify the gaps in the knowledge base the proposed research will address. Describe any work the principal investigator has done which led to this proposal or that was done specifically to pilot test aspects of what is being proposed (i.e., instruments, acceptance to participate and attrition rates, etc.).

c. Explanations of Concepts and Working Definitions. Many of the variables with which MCH research is concerned are abstract in nature, e.g., maternal-infant bonding. Because of their abstract quality these variables are difficult to grasp. It is therefore imperative that investigators using these variables spell out what is generally meant by the concepts and what unique meanings (if any) they are to assume in the proposed research. If possible, this explanation of concepts should refer to published works to justify the general or specific meanings that are being used.

d. Hypothesis and Specification of Variables. Present the specific questions that are to be answered by the study. These should include not only predictions as to findings (hypotheses) but also justifications for the predictions. A summary table of the variables, classified as independent, intervening, mediating, and dependent, etc. should be presented, specifying the nature of the variables, the measures to be employed as indicators for these variables, and the units and levels of measurement of the indicators. If possible, construct and present a model or graphical representation of the set of relationships held to be operative among the variables. **Make sure that there is congruence between the associations depicted by the graphic model, the table of variables, the statement of hypotheses, and the plan for data analysis**.

The statement of the problem, together with the review of the literature and the explanations of concepts and working definitions, should delineate the conceptual framework of the study and, thus, support the hypotheses proposed, the specific sets of variables selected for the study, and the plan for data analysis. Note that covering these subjects according to instructions does not assure adequate conceptualization. The investigator must weave all of these elements into a coherent whole or total rationale that would serve as justification for the research as proposed.

e. Tests and Measurement. Describe the data and how they will be collected, including the specific tests, questionnaires, interviews, scales, and other data gathering measures that are to be used. Attach copies (in the Appendix) of all materials specifically constructed for the study. For these investigator-developed measures, describe the assumptions and pre-test results, including validity and reliability determinations. When standardized instruments are to be used, care should be exercised to select the most appropriate for the research operation among those that are available. It is not necessary to submit copies of these instruments if they are of wide acceptance in the field. Their use should be justified and information should be presented as to their validity and reliability.

f. Study Design. Design is the logical strategy of the study. As such it is intricately tied to standards of scientific inquiry, to proof, and to the degree of validity that can be placed on a set of research findings.

In this section of the research plan include:

1. The name of the study design (e.g., descriptive correlational, case control, randomized clinical control trial, etc.); and

2. A description of the design chosen and what it entails for the proposed study, including weaknesses and strengths.

If a randomized clinical control trial is being proposed, be sure to specify:

1. Whether or not a log will be kept to document who qualified for the study and what was her/his disposition.

2. The method of randomization.

3. Who will allocate study subjects to treatments.

4. What controls will be instituted to minimize biases in allocations.

5. What the experimental and control treatment alternatives consist of, with differences and similarities clearly delineated.

6. What measures will be taken in the laboratory, clinical, or field situations to assure that the experimental and control treatments are delivered exactly as the study calls for.

7. What plans are being proposed for handling inequalities among groups once the existence of an inequality has been recognized.

g. Population Description and Sampling Plan. Describe the population of cases from which the sample(s) for the study will be selected and explain the criteria for selection and the process by which they will be selected. State the sample(s) size(s) and justify in terms of statistical power. Describe assumptions made as to attrition of subjects and what will be done to minimize it or to remedy it if it does occur.

The Title V Program administered by MCHB is intended to address the health needs of <u>all</u> mothers and children, including class, racial, and ethnic subgroups. It is the policy of the Bureau that members of minority groups be included in all research proposed, unless a clear and compelling rationale and justification establishes inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. It should be noted that these inclusionary requirements have important consequences for practically all components of a research operation, but particularly for sample size requirements (and related power analyses) and for cultural and language appropriateness, reliability and validity of tests and measures. If minorities are excluded, a clear and compelling rationale for exclusion and inadequate representation must be provided. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. When proposing clinical trials,

show whether clinically important class/race/ethnicity differences are expected. The trial should be designed to accommodate any such differences. Given that class, racial, and ethnic differentials currently exist and are widening in practically every major indicator of maternal and child health, the MCHB suggests that applicants should routinely approach the formulation of their research with considerations of class, race, and ethnicity in mind and with the intention of conducting class-, race-, and ethnicity-specific analyses whenever appropriate and possible.

Summarize the class, racial, and ethnic composition of the study sample(s) as per Table A. It is likely that the nature of the study may require greater specificity in terms of national origin (use example Tables B & C as guide).

Table A. Breakdown of Class, Racial, and Ethnic Compositions in the study

	American Indian or Alaskan Native	Asian or Pacific Islander	Black, not of Hispanic Origin	Hispanic	White, not of Hispanic Origin	Other or Unknown	Total
Low SES							
Middle SES							
High SES							
Unknown							
Total							

Table B. Breakdown of the Asian Category into Subcategories

	Chinese	Japanese	Filipino	Others (specify)	Total
Low SES					
Middle SES					
High SES					
Unknown					
Total					

Table C. Breakdown of the Hispanic Category into Subcategories

	Mexican-American	Central-American	Puerto Rican	Others (specify)	Total
Low SES					
Middle SES					
High SES					
Unknown					
Total					

h. Plan for Data Analysis. Describe in a stepwise manner how the data will be analyzed in order to answer the research questions and/or hypotheses posed for the study. Be specific; restrict the description to how project data will be systematically approached. Use one or two examples of study questions or hypotheses and show how the data will be analyzed; justify the statistical techniques chosen.

i. Time Schedule. Portray graphically the time that has been allowed for each major phases of the study, e.g., recruitment of personnel, testing of questionnaire, sample selection, etc. For the first year of the requested project period, depict the time estimates in terms of months; thereafter, in years.

j. Financing. State whether this proposal has been submitted or will be submitted to any other Federal agency or private foundation for consideration and review. Explain the amount of support available or expected for this project from other sources.

If there are going to be multiple sources of support, present the budget as required on form pages 4 and 5 of PHS 398 (Rev. 4/98), expanded to include the amounts promised or committed by the other prospective sources of support. Offer evidence of these sources= commitment and certainty of support. This should give the reviewers and the awarding officials of MCHB an idea of how much the entire study will cost and what proportion of such overall cost the MCH Research Program is being asked to defray. It should be noted that no grant will be issued by MCHB until evidence has been submitted to the Research Program Office that the expected contributions of all sources have been realized. It should also be noted that, in situations of multiple sources of support, MCHB will not assume the contributions defaulted by others even if it means that the project cannot be supported, or if it has started and has to be terminated before the completion of the approved project period.

k. Human Subjects. Abide by the instructions on pages 17-18 of PHS Form 398

(Rev. 4/98)

l. Literature Cited. Follow instructions on pages 18-19 of PHS Form 398 (Rev. 4/98)

NOTE: SKIP "f. Vertebrate Animals." It does not apply to MCHB.

m. Consortium/Contractual Arrangements. Follow instructions on page 19 of PHS Form 398 (Rev. 4/98).

n. Consultants. Follow instructions on page 19 of PHS Form 398 (Rev. 4/98).

10. Appendix. Page 19**.** Include **six** collated sets instead of **five**.

11. Checklist. Omit **"Vertebrate Animals"** from the list of assurances and certifications. Otherwise, abide by the rest of the instructions. **Please note the following requirements related to research misconduct:**

Each institution that receives or applies for a research, training, or research-related grant or cooperative agreement under the Public Health Service Act must certify that the institution has established administrative policies as required by Final Rule, 4 CFR 50, Subpart A, AResponsibilities for PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science,@ and that it will comply with those policies and the requirements of the Final Rule.

The signature of the official signing for the applicant organization on the face page of the application serves as certification that:

(a) The institution will comply with the requirements of the PHS regulations on responsibilities of awardee and applicant institutions for dealing with and reporting possible research misconduct, 42 CFR Part 50, Subpart A;

(b) The institution has established policies and procedures incorporating the provisions set forth in 42 CFR Part 50, Subpart A;

(c) The institution will provide its policies and procedures to the Office of Research Integrity upon request; and

(d) At the end of each calendar year, all institutions with research, training, or research-related grants or cooperative agreements will make a submission (PHS Form 6349) comprising an aggregate report

on their allegations, inquiries, and investigations handled in the previous year. Form 6349 will be sent automatically to all PHS awardees by the Office of Research Integrity at the end of each calendar year.

SECTION II - SUBMITTING YOUR APPLICATION

A. INSTRUCTIONS

Page 21 (1) Does not apply to MCHB.

Page 21 (2) Disregard everything after "If appropriate..."

Page 21 (3) **Six** exact, single-sided copies of the application are required by MCHB.

Page 21 (4) **Six** collated sets of appendix material are required by MCHB.

SEND APPLICATION TO THE FOLLOWING ADDRESS:

Grants Management Officer, MCHB

Grants Application Center (CFDA #93.110RS)
1815 N. Fort Myer Drive
Suite 300
Arlington, VA 22209
Telephone: 1-877-477-2123
hrsagac@hrsa.gov

DO NOT SEND IT TO THE CENTER FOR SCIENTIFIC REVIEW (CSR), NATIONAL INSTITUTES OF HEALTH (NIH). In the event that such misdirection happens, it will be the responsibility of the applicant organization to retrieve the application from the CSR and resubmit same to the address listed above. In misdirection situations, acceptance by the MCHB is not assured for the originally intended deadline unless the application is received 7 weeks prior to the review date. Otherwise, it will be returned to the applicant.

Disregard everything between **"**If express...**"** and **"**...award schedule:**"**

For receipt, review, and award cycles information see the DESCRIPTION OF PROGRAM section of the APPLICATION GUIDANCE MATERIAL document.

Page 22. Paragraph 5. Line 10. Substitute "...the scientific review administrator of the CSR...**"** for "the Chief, Research Branch or its deputy.

Page 22. Paragraph 6. Simultaneous submissions of identical applications are permitted.

Page 22. Paragraph 7-8. Disregard.

B. THE PEER REVIEW PROCESS

Page 22-23. Disregard. Substitute the following:

For a description of the Peer Review Process refer to the **DESCRIPTION OF THE PROGRAM** section of the APPLICATION GUIDANCE MATERIAL document.

Soon after the submission deadline, the Grants Management Branch (GMB), through the HRSA Application Center, will acknowledge receipt of the research application and its acceptance for review by the Maternal and Child Health Research Review Committee. As soon as possible after the Committee meeting, the principal investigator will be notified of the outcome of the review. Depending on the workload, a summary statement of the Committee=s findings and recommendations may be enclosed together with the letter communicating the outcome of the review or may be sent at a later date.

Inquiries about the review status of the application after its receipt has been acknowledged by GMB through the HRSA Application Center and about the specifics of the summary statement should be addressed to:

Chief, Research Branch
Division of Research, Training and Education
Maternal and Child Health Bureau
Room 18A-55, Parklawn Building
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-2190.

When making inquiries, refer to the MCR- number found in the acknowledgment of receipt communication, the name of the principal investigator, and the title of the application.

(Reprinted from *MCH Research Exchange*, Volume 1, Number 2, December 1995)

5—Developing a Research Application and Applying to Federal Sources of Support

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To some, developing a research application is an art that few can master. For others, it is like baking a cake: If you know the recipe, then you can do it as well as anyone else. There are elements of truth in both of these assertions. Developing a research application is, above all, a demanding, sometimes daunting task. It requires a willingness to spend time doing homework prior to writing, and a willingness to acquire new knowledge and skills on one's own or through cooperative ventures with colleagues of other disciplines. It also requires the motivation to compete and, above all, the ability to withstand criticism and cope with rejection. It also requires practice, practice, practice.

For the uninitiated, this article offers a primer on what is involved in developing a winning research application. For experienced applicants, this information may be old hat. For both experienced and new applicants, however, this article provides specific information about the MCH Research Program of the Maternal and Child Health Bureau. We hope this article will motivate prospective applicants, whether experienced or not, to both plunge into the task of research application writing and apply to the MCH Research Program.

Sources of Support

One of the first steps in preparing to apply for research support is identifying the possible sources of that support. Generally speaking, there are two major sources: federal agencies and private foundations. There is overlap in subject matter and priorities within as well as between these two funding sources. A good funding strategy is to capitalize on this overlap by submitting an application to more than one funding organization and preparing the ground for sharing support between funding
sources if the application is recommended for approval by more than one review group. Sharing support is a necessity if the amount of funding required is in excess of what a single funding agency can ordinarily afford. The degree of success in securing shared support will depend on how important and/or topically current the proposed research is at the time the application is reviewed. Success also depends on how good a salesperson the grant writer is. Both are important components of what is called "grantsmanship."

There are five main sources of federal support for MCH research. These are: (1) MCHB; (2) the National Institute of Child Health and Human Development; (3) the National Center for Nursing Research; (4) the Agency for Health Care Policy and Research; and (5) NIMH. The Division of Research Grants (DRG) of the National Institutes of Health (NIH) is the central intake unit for all research applications addressed to the federal units noted above, except for MCHB. Because MCHB has a review process

independent from that of NIH, applicants may submit the same research proposal to both MCHB and anyone of the federal agencies covered by the NIH central intake unit. However, the same application cannot be submitted to more than one agency served by the NIH intake unit. Applicants may, however, specify to the DRG which institute—and which review group within that institute—they want their application to be assigned to. Otherwise, DRG will assign the application to the institute and review group they feel is most appropriate. Any application recommended for approval by both MCHB and an NIH review group can only be funded in full by one or the other; however, shared funding is possible through an interagency transfer of funds.

Private foundations vary in how they handle the application process. As a rule, the process is less formal than in the federal agencies, and thus approval is more likely to be influenced by discussions or negotiations between the prospective applicant and foundation officials. Often, private foundations have narrow bands of interest that restrict the nature of the research they fund.

What Constitutes a Winning Proposal

A research application has an increased chance of approval if it contains the following: (1) an important and/or original research question or topic; (2) a well-written, reasonably detailed, and technically appropriate plan for conducting the research; and (3) a realistic budget.

What is meant by "important" or "original"? "Important" means that the research question is a topic of current interest (e.g., pediatric AIDS), or that it promises to expand the scientific knowledge base in some significant way, or that the expected findings could be readily applied toward amelioration of an existing problem. "Original" means that it represents a considerable departure from the norm or that it represents a different twist to something already part of the existing knowledge base. An exception to the rule of originality is the purposive validation of prior research.

How well a research application reads depends not only on organization but also on the choice of words, the amount of detail provided, and the degree to which the different ideas and sections in the written protocol flow into a coherent whole. Well-written applications do not evolve effortlessly, or overnight. They require the careful nurturing of a multidisciplinary group of professionals over several months. Additional months of rewriting and careful review by critical coworkers are essential.

Technical appropriateness refers to a match or fit between the nature of the research problem as stated, the circumstances under which the research will be done, and the most efficient study design, measurement, and data collection approaches that are possible. Components of what is meant by technical appropriateness include knowing when to sacrifice reliability and validity for the sake of human subject considerations or for the sake of staying within the amount of support that can be obtained. Such compromises, if communicated and argued logically and forcefully in the application document, are well received by reviewers even if the resulting technical quality of the research might be less than optimal.

The term "efficiency" refers to a project's ability to answer the research questions proposed at an acceptable level of scientific rigor and at the least possible cost. Efficiency is entering more and more into the review process as a criterion for approval or disapproval. Applicants increasingly must justify the efficiency of their study design and research approaches. This requires that applicants state in the application the designs and approaches that have been considered

and discarded as a means of justifying their selection.

A realistic budget is one that requests slightly more funding than may be needed to do the task at hand and one that stays within the bounds of affordability of the support source selected. Requesting a slightly higher budget is warranted since it is difficult to estimate the real costs of a research operation with precision. This is not a license to inflate costs in order to obtain fancy equipment or pay for departmental training costs. Inflated budgets are quickly recognized as such by study section reviewers and have a negative effect on the entire review process.

Having provided a general sketch of what constitutes a good application, let us turn now to the specifics of developing an application that has a reasonable chance of being both recommended for approval and funded. We will approach this indirectly by describing the reasons why most applications get rejected by the Maternal and Child Health Research Review Committee.

Reasons for Disapproval

The percentage of all new applications reviewed and rejected in federal research supporting agencies such as NIH and MCHB ranges from 55 to 85 percent, depending on the program and type of research. As a rule, new applications reviewed by the NIH study sections are recommended for approval at a much higher rate than those reviewed by MCHB. (For the past three years, MCHB's approval rate has been about 15 percent.) Does this indicate that MCHB's review process is more demanding NIH's? Not necessarily. This disparity is most likely the result of differing volumes of applications and other factors influencing the review process. The practical result is that although the two agencies differ in the percentage of new applications recommended for approval, the percentage of all new applications actually funded is approximately the same.

Many reasons are conjectured by applicants for the relatively low rate of success in receiving research support. Among these are: (1) unrealistic standards of excellence on the part of review panels; (2) favoritism toward established investigators and/or acquaintances; and (3) lack of research experience and review know-how on the part of reviewers. While in some limited instances any of these reasons can enter into the disapproval equation, the fact is that most research applications are rejected because of faulty conceptualization and/or methodological flaws.

Conceptualization

What is conceptualization? Essentially, it is a process of explication and generalization that takes seemingly unconnected theoretical and empirical facts and transforms them into a coherent whole and a total rationale for justifying the proposed research. Conceptualization is said to have occurred when the following three conditions have been met: (1) The cause and effect assumptions binding the purpose of the investigation have been stated; (2) the major concepts to be used have been explicated; and (3) the hypotheses relevant to the research questions have been specified.

Conceptualization is an important—if not the most important—activity in a research undertaking. Inadequate conceptualization is a common flaw in disapproved applications submitted to the MCH Research Program. The typical approach found in these disapproved applications is to state the research problem in general terms and then launch into the specification of variables, study design, and plans for data analysis, with no

effort to place the proposed research in a wider theoretical and/or empirical framework. Consequently, reviewers are at a loss to determine not only the significance of the intended research but also the appropriateness of much of what is proposed. Faulty conceptualization is at the root of such methodological flaws as data collection overkill, disregard for validity and reliability considerations, and inappropriate use of statistical procedures.

In research applications, the conceptualization component is woven through such sections as statement of the problem, review of the literature, hypotheses and specification of variables, and explanation of concepts. Note that covering these subjects according to instructions does not assure adequate conceptualization. The investigator must weave all of these elements into a coherent whole with economy and simplicity of assumptions. This is what members of study sections call tight conceptualization. There is nothing more selling in a research application than a tight conceptualization. Methodological deficiencies are apt to be given less significance when a tight and lucid conceptualization of the research problem has preceded the plans for its execution.

How does one develop a tight or parsimonious conceptualization of a research problem? Simply put, through total immersion in the nuances of the research problem. The first step is to reflect on the research problem, then conduct an exhaustive review of the empirical and theoretical literatures. This is also the time to begin informal consultation by diplomatically eliciting information from learned colleagues or more formally soliciting expert opinions. Total immersion over a sufficient length of time leads to clarity of thought and the logical exposition of ideas and assumptions about the research problem. A fast-approaching deadline or the need to generate funds to cover salary expenses may then provide the impetus to commit to paper the conceptualization that has been developed.

Methodology

The research plan component of an application is merely a declaration of how one will execute the research in the field or laboratory situation. The technical component calls for a knowledge of study design, measurement approaches, and sampling and statistical techniques. Most applications get rejected for one or more technical reasons. The two most common are methodological weaknesses and lack of detail about essential aspects of the research operation. Since methodological weaknesses frequently overlap with lack of detail, it is justifiable to say that research methodology constitutes one of the most important barriers to the successful navigation of the review process.

What methodological concerns are most frequently raised by reviewers of research applications? Often, the methodological flaws seem to be simple acts of omission or failure to explicate on the part of the investigator. Other times, they appear to reflect lack of knowledge about the technical nuances of doing research. In the first instance, the common failing seems to be an expectation on the part of the investigators that the reviewers will assume that what needs to be done will be done, even if not stated. It is important to note that errors of omission and failures to explicate frequently occur despite the investigator having been given very detailed instructions on what to include in the research plan and at what level of specificity.

How can one develop an appropriate and methodologically sophisticated research plan that does justice to the complexity of the research problem at hand and becomes a selling point in the application process? One essential prerequisite is achieving the tight conceptualization of the research problem discussed earlier. The technical requirements

of a research operation largely flow from the way in which the research problem was conceptualized. Efficient use of research experts such as biostatisticians, psychometricians, and epidemiologists early in the formulation of the research problem helps considerably. An alternative approach is to make the design of a research project an interdisciplinary team effort from the start. This alternative requires a lot of give and take, particularly at the formulation stage, and one professional, usually the principal investigator of record, must assume a leadership role in putting the pieces together. If the process is not carefully orchestrated and executed, the result is a disjointed product quickly recognized by reviewers as a project developed by committee that is likely to flounder in the execution stage.

The number of variables to be included in an investigation and the amount of data to be collected are, as a rule, a function of how well the research problem has been conceptualized. If the overall conceptualization is tight, the number of variables will be relatively small and redundancy in measurement will be moderate and purposive. On the other hand, if conceptualization is loose, the degree of specificity in what is to be measured will be minimal, and data collection will be extensive, redundant, and without an apparent focus.

Most applications received by the MCH Research Program suffer from some degree of data collection overkill. In some cases, this reflects purposive research agendas rather than faulty conceptualization. The rationale in some cases seems to be to increase the amount of data for later use in exploratory analyses or to create a fail-safe situation in which a standby set of variables will be available to fall back on if the main variables do not prove to be significant. In other cases, the nature of the research itself may dictate data collection overkill. Multiple measures may be necessary to tap the same variables for the purposes of convergent validity or to develop more parsimonious measures through data reduction techniques such as factor analysis.

However, most cases of data collection overkill seen in the applications submitted to the MCH Research Program are largely unintentional, and appear to derive from loose conceptualization. While lack of research experience appears to play a significant role in these cases, the problem can frequently be found in the applications of experienced researchers as well. In general, the problem with all types of data collection overkill is that the surplus data seldom get analyzed, which ultimately translates into wasted resources and higher costs of doing research.

Few of the applications received at the MCH Research Program even partially meet the textbook requirement of fully explaining the procedures for implementing the study design. This is particularly true for applications proposing randomized clinical control trials or field experiments. In this kind of application, the tendency is to state that a trial is being proposed without bothering to describe the many procedural details required to ensure that the chosen design will be executed faithfully.

Research applications grossly underestimate the significance of failing to describe how the study design is to be operationalized in the actual research situation. For example, randomization in clinical trials is known to offer the following benefits: (1) It protects the study from selection bias; (2) it ensures that, on the average, the groups will be equivalent or balanced; and (3) it provides the basis for statistical inference. These advantages can be easily compromised by conscious or unconscious biases introduced

when study personnel apply the criteria for entry into the study and/or when they assign subjects to treatments. Similarly, failure to deliver treatments exactly as called for in the protocol weakens the power of the statistical analyses and may lead to rejection of a beneficial treatment or the acceptance of an ineffective one.

A large number of the applications disapproved by the MCH Research Program propose small samples of convenience. Moreover, few of the applications state what the clinically or scientifically important differences are, or what the probability of detecting these differences will be. In other words, the applications fail to justify sample size in terms of statistical power. Studies using inappropriately small samples are doomed to miss clinically or scientifically relevant differences, and thus are unethical in their use of subjects and resources.

Withdrawal of subjects from studies can be due to subjects choosing to drop out or to investigators' design, usually in the analytical phase. Regardless of the reason, attrition plays havoc with data analysis and interpretation. The most typical approach to the subject of attrition in applications rejected by MCH Research Program reviewers is not mentioning the subject at all, or, if it is mentioned, dismissing it optimistically without supportive evidence. Underestimating attrition is also common, particularly in situations where samples of convenience are to be used and where the pool of subjects is inherently small, as with conditions of low incidence and low prevalence. Failure to plan for monitoring subject attrition and doing something about it if it occurs to a significant degree is another common problem in applications.

What If Rejected?

Since 55–85 percent of all new applications are rejected the first time they go through the review process, not being recommended for approval should not be taken as a personal affront or failure. One should withhold judgment until receiving the "pink sheets" or summary statement of the review. Rejection in many cases will turn out to be a prelude to a better written, technically stronger, revised application—one with a two- or three-fold greater chance of being approved. Rejection should not be viewed as reflecting some deficiency or weakness inherent in the review process (e.g., a bias against young and new investigators). Rather, view it for what in most cases it is: an imperfect but honest and well-meant evaluation and critique by highly trained and experienced reviewers.

Summary statements or pink sheets (white sheets in the case of MCHB) are lengthy, detailed communications providing a consolidated statement of the evaluation that is done for each application. Pink sheets are the key to developing improved, more competitive applications. Summary statements should be read carefully and more than once to ensure that all descriptions of weaknesses, errors of omission and commission, etc. are identified and understood. An “Introduction” section should be added to the “Research Plan” of all revised applications addressing all the issues and concerns raised by reviewers in the prior review , and changes relating to them should be identified in the body of the text either through bracketing, indenting, or changing of typography. If an applicant strongly disagrees with a particular criticism, she or he should develop a considered, logical argument refuting the reviewers' comments or recommendations. The “Introduction”section is a good place to do that. Most agencies will accept a maximum of two revisions of a previously submitted application. Some agencies instruct the applicant in the summary statement of the first submission not to revise and/or reapply if the study section has made such a recommendation.

Summary

In general, developing a fundable research application calls for hard work, painstaking attention to detail, and total commitment to the task at hand. Allowing ample time to flesh out the complexities and details is of primary importance. With a first submission, rejection or disapproval is the norm, so the applicant should always be prepared to revise and resubmit. Revised applications have a much greater chance of being approved, but success depends upon careful scrutiny of what the reviewers had to say and a willingness to revise the application in accordance with their comments and recommendations.